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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/593,591	06/13/2000	Gary K. Michelson	101.0078-00000	5619

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EXAMINER

PREBILIC, PAUL B

ART UNIT PAPER NUMBER

3738

DATE MAILED: 09/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/593,591

Applicant(s)

MICHELSON, GARY K.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-147 is/are pending in the application.
- 4a) Of the above claim(s) 130-147 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-129 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 13 June 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6,8. 6) ☐ Other:

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Newly submitted claims 130-147 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The claims are drawn to a method of use and not an implant as originally set forth. Therefore, since a different statutory class is set forth and it is patentably distinct from the original claims, the claims have not been examined on their merits.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 130-147 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the features of claims 23, 24, 27, 28, 31, 35, 64, 65, 68, 69, 107, 108, 111, and 112 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. Since the omitted elements would be difficult if not impossible to be shown in drawings without the inclusion of new matter, the Examiner strongly recommends that the claims be cancelled rather than providing proposed drawings.

Cancellation of the claims or proposed drawing corrections are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities:

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Throughout the specification, the patent application serial numbers should be updated with the patent numbers if they have such in order to further identify them.

Appropriate correction is required.

Claim Objections

Claims 23, 24, 31, 35, 64, 65, 107, 108, and 112 are objected to because of the following informalities:

With regard to claims 23, 24, 64, 65, 107 and 108, after careful review of the specification, it could not be found where a second opening passing through the upper and lower surfaces has antecedent basis from the specification.

With regard to claim 31 and 35, the combination of bone and composite material is not supported by the specification. These two materials are independently disclosed and never stated as being used in combination other than in the original claims. For this reason, the Examiner suggests canceling these claims since there is no teaching on how to make a combination implant of the two.

With regard to claim 112, "said lock" lacks antecedent basis from claim 110. It may be that claim 112 was supposed to depend from claim 111.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-22, 25-35, 43-63, 66-77, 85-106, 109-119 and 127-129 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Boyle et al (US 6,277,149); see the whole document, especially Figures 10, 12, and 15.

With regard to claims 26-29, 67-70, and 110-113, the location and composition of vertebral bodies is not defined. Therefore, the claim language is read on by the bone particles or bone growth material inserted into the opening (326) for example; see column 4, lines 10-13.

With regard to claim 29 specifically, since the screw is not positively claimed as part of the implant, its structure is not viewed as being positively required by the claim. For this reason, it is interpreted as an inferential recitation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23, 24, 64, 65, and 107-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al (US 6,277,149) in view of Zdeblick et al (US 5,669,909). Boyle et al meets the claim language but fails to disclose more than one bore through the upper and lower surfaces as claimed. Zdeblick et al, however, teaches that it was known to have more than one hole in similar implants; see the figures. Hence, it is the

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Examiner's position that it would have been obvious to have two or more holes in the Boyle et al implant for the same reasons that Zdeblick et al has the same and in order to promote greater ingrowth.

Claims 36-42, 72, 78-84, and 120-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al (US 6,277,149) alone.

With regard to claims 36-42, 78-84, and 120-126, Boyle et al meets the claim language except for the types of growth promoting substances claimed. However, the Examiner posits that the type of growth promoting substance would have been prima fascia obvious over Boyle et al alone because there is no criticality for such types shown or demonstrated. For example, in column 4, lines 10-13, Boyle discloses putting bone growth material into the opening (26). The specific type of bone implant material claimed would amount to a substitution of a functionally equivalent bone growth material for another one as disclosed by Boyle. For this reason, it would have been prima fascia obvious to an ordinary artisan to substitute one bone growth material for another since the other one would function equally well.

With regard to claim 72, Boyle et al does not disclose the use of a bioresorbable plastic as claimed. However, the Examiner hereby gives Official notice that bioresorbable plastics are known and used in the art. Hence, it is the Examiner's position that it would have been obvious to do the same in the Boyle et al invention for the same reasons that the prior art uses the same. In particular, Gross et al (US 5,306,308) teaches that it was known to coat similar implants with the bioresorbable plastic polylactide in order to encourage bone ingrowth. Therefore, it would have been

obvious to coat the Boyle et al implant with polylactide in order to promote bone ingrowth as taught by Gross et al.

Response to Arguments

Applicant's arguments filed May 28, 2002 have been fully considered but they are not persuasive.

In particular, Applicant argues that Boyle fails to disclose a substantially straight front edge with a curved back edge. However, Applicant is directed to Figures 7 and 19, which show a structure that reads on this claim language. For this reason, the claim language is considered to be fully met in this regard.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned problem is corrected.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9301.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
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